EUROPEAN COMMISSION

Brussels, 17.2.2012
C(2012)1190 final

COMMISSION IMPLEMENTING DECISION

of 17.2.2012

amending the marketing authorisation granted by Decision C(2004)851 for "Faslodex - Fulvestrant", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to the applications submitted on 20 November 2011 by AstraZeneca UK Limited under Article 16 of Regulation (EC) No 1234/2008,

Having regard to the opinions of the European Medicines Agency, formulated on 19 January 2012 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinions on the major variations type II and of the need to amend the marketing authorisation for the medicinal product "Faslodex - Fulvestrant" which is entered in the Community Register of Medicinal Products under numbers EU/1/03/269/001-002.

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1 OJ L 136, 30.4.2004, p. 1.

2 OJ L 334, 12.12.2008, p. 7.

(2) The marketing authorisation should be updated and Decision C(2004)851 of 10 March 2004 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)851 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to AstraZeneca UK Limited, Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom.

Done at Brussels, on 17.2.2012.

For the Commission
Paola TESTORI COGGI
Director-General